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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,687	09/28/2000	David Wallach	WALLACH=25	7238

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EXAMINER
LAMBERTSON, DAVID A

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1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/671,687	Applicant(s) WALLACH ET AL.	
	Examiner David A Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, and 20, drawn to an isolated protein that binds to NF-κB and TRAF2, classified in class 530, subclass 300 or 350.

II. Claims 5-14, 16, 17 and 19, drawn to an isolated DNA molecule encoding a protein that binds to NF-κB or TRAF2 and the corresponding vectors and host cells containing the vectors, classified in class 536, subclass 23.1.

III. Claim 15, drawn to an antisense molecule, classified in class 536, subclass 24.5.

IV. Claim 18, drawn to a method for producing a polypeptide, classified in class 435, subclass 41.

V. Claims 21-24, drawn to an antibody, classified in class 424, subclass 130.1.

VI. Claim 25, drawn to a method for mediating the activity of NF-κB or TRAF2 in a cell by treating said cell with a protein, classified in class 435, subclass 7.1.

VII. Claims 25 and 26, drawn to a method for mediating the activity of NF-κB or TRAF2 in a cell by treating said cell with a DNA molecule, classified in class 435, subclass 6.

VIII. Claim 27, drawn to a method for mediating the activity of NF-κB or TRAF2 in a cell by treating said cell with antibodies, classified in class 435, subclass 7.1.

IX. Claim 28 and 29, drawn to a method for mediating the activity of NF-κB or TRAF2 in a cell by treating said cell with antisense, classified in class 435, subclass 6.

X. Claim 30, drawn to a method for mediating the activity of NF-κB or TRAF2 in a cell by treating said cell with a ribozyme, classified in class 435, subclass 7.1.

XI. Claim 31, drawn to a method for identifying and isolating a protein that binds to both NF-κB and TRAF2 using a two step two-hybrid analysis, classified in class 435, subclass 29.

XII. Claim 32, drawn to a method for preventing a pathological condition associated with NF-κB induction by administering a protein to a patient, classified in class 424, subclass 9.1.

XIII. Claim 32, drawn to a method for preventing a pathological condition associated with NF-κB induction by administering a DNA molecule to a patient, classified in class 424, subclass 9.2.

XIV. Claim 33, drawn to a method for identifying a ligand that binds to a protein that binds to NF-κB or TRAF2 using chromatographic measures, classified in class 530, subclass 413.

XV. Claim 34, drawn to a method for identifying a ligand that binds to a protein that binds to NF-κB or TRAF2 using a two-hybrid system, classified in class 435, subclass 7.31.

XVI. Claim 35, drawn to a method for identifying and producing a ligand that modulates TRAF2 and/or NEMO, classified in class 435, subclass 7.1.

XVII. Claim 36, drawn to a method to identify and produce a ligand that modulates the activity modulated by a protein that binds to NF-κB or TRAF2, classified in class 435, subclass 7.1.

XVIII. Claim 37, drawn to a method to identify and produce a molecule that modulates the activity modulate by NAP in a direct or indirect manner, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Groups II, III, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. An isolated protein (Group I) and a DNA molecule (Group II), an antisense molecule (Group III) and an antibody (Group V) are unrelated because each molecule has a different chemical structure, therefore a different function, and are considered to be separate inventions. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group I and Group IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a materially different process, such as solid-state

synthesis, or a non-recombinant methodology. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group I and Groups VI, XIII, XIV and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced with a materially different product, such as a DNA molecule (in the case of Groups XIV and XVII, the DNA molecule can be used in a two-hybrid system). A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group I and Groups VII-XII, XV, XVI and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve different modes of operation and functions. An isolated protein (Group I) is unrelated to a method for modulating NF-κB activity using DNA (Group VII), an antibody (Group VIII), an antisense molecule (Group IX) or a ribozyme (Group X), a method for identifying molecules that bind to NF-κB and TRAF2 using a two-hybrid system (Group XI), a method for preventing NF-κB associated pathology using DNA molecules (Group XII), a method for identifying a ligand that binds to an NF-κB and TRAF2 binding protein by two-hybrid analysis (Group XV), a method for identifying a ligand that modulates TRAF2 and/or NEMO activity (Group XVI) and a method for identifying a molecule that modulates NAP directly or indirectly (Group XVIII) because the

recited methods utilize molecules that are different from the isolated protein in practicing the methods, and thus have different modes of operation and resulting functions. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group II and Groups III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. A DNA molecule (Group II), and an antisense molecule (Group III) and an antibody (Group V) are unrelated because each molecule has a different chemical structure, therefore a different function, and are considered to be separate inventions. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group II and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. A DNA molecule (Group II) is unrelated to a method of making a protein (Group IV) because the function of the method is to make a molecule that is unrelated in structure to the DNA product. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group II and Groups VI, VIII-XI, XIII, XIV, and XVI-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and functions. A DNA molecule (Group II) is unrelated to a method for modulating NF-κB activity using protein (Group VI), an antibody (Group VIII), an antisense molecule (Group IX) or a ribozyme (Group X), a method for identifying molecules that bind to NF-κB and TRAF2 using a two-hybrid system (Group XI), a method for preventing NF-κB associated pathology using protein (Group XIII), a method for identifying a ligand that binds to an NF-κB and TRAF2 binding protein by affinity chromatography (Group XIV), a method for identifying a ligand that modulates TRAF2 and/or NEMO activity (Group XVI), a method to identify a ligand that modulates the activity modulated by a protein that binds NF-κB or TRAF2 (Group XVII) and a method for identifying a molecule that modulates NAP directly or indirectly (Group XVIII) because the recited methods utilize molecules that are different from the DNA molecule in practicing the methods, and thus have different modes of operation and resulting functions. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group II and Groups VII, XII and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced using a materially different product, such as a protein (in the case of Group XV, by performing affinity

chromatography). A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group III and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. An antisense molecule (Group III) and an antibody (Group V) are unrelated because each molecule has a different chemical structure, therefore a different function, and are considered to be separate inventions. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group III and Groups IV, VI-VIII, and X-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and functions. An antisense molecule (Group III) is unrelated to a method for making a protein (Group IV), a method for modulating NF-κB activity using protein (Group VI), a DNA molecule (Group VII), an antibody (Group VIII), or a ribozyme (Group X), a method for identifying molecules that bind to NF-κB and TRAF2 using a two-hybrid system (Group XI), a method for preventing NF-κB associated pathology using DNA (Group XII), a method for preventing NF-κB associated pathology using protein (Group XIII), a method for identifying a ligand that binds to an NF-κB and TRAF2 binding protein by affinity chromatography (Group XIV), a method for

identifying a ligand that binds to an NF-κB and TRAF2 binding protein by two-hybrid analysis (Group XV), a method for identifying a ligand that modulates TRAF2 and/or NEMO activity (Group XVI), a method to identify a ligand that modulates the activity modulated by a protein that binds NF-κB or TRAF2 (Group XVII) and a method for identifying a molecule that modulates NAP directly or indirectly (Group XVIII) because the recited methods utilize molecules that are different from the antisense molecule in practicing the methods, and thus have different modes of operation and resulting functions. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group III and Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced using a materially different product such as a protein. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. A process for producing a protein (Group IV) is unrelated to an antibody (Group V) because the method produces a compound that is chemically distinct from an antibody, therefore the method has a different mode of operation

and resulting function. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group IV and Groups VI-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. A method for producing a protein (Group IV) is unrelated to a method for modulating NF-κB activity using protein (Group VI), a DNA molecule (Group VII), an antibody (Group VIII), an antisense molecule (Group IX), or a ribozyme (Group X), a method for identifying molecules that bind to NF-κB and TRAF2 using a two-hybrid system (Group XI), a method for preventing NF-κB associated pathology using DNA (Group XII), a method for preventing NF-κB associated pathology using protein (Group XIII), a method for identifying a ligand that binds to an NF-κB and TRAF2 binding protein by affinity chromatography (Group XIV), a method for identifying a ligand that binds to an NF-κB and TRAF2 binding protein by two-hybrid analysis (Group XV), a method for identifying a ligand that modulates TRAF2 and/or NEMO activity (Group XVI), a method to identify a ligand that modulates the activity modulated by a protein that binds NF-κB or TRAF2 (Group XVII) and a method for identifying a molecule that modulates NAP directly or indirectly (Group XVIII) because the recited methods are intended to achieve a different end result, and thus have different modes of operation and resulting functions. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group V and Groups VI, VII, and IX-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. An antibody (Group V) is unrelated to a method for modulating NF-κB activity using protein (Group VI), a DNA molecule (Group VII), an antisense molecule (Group IX), or a ribozyme (Group X), a method for identifying molecules that bind to NF-κB and TRAF2 using a two-hybrid system (Group XI), a method for preventing NF-κB associated pathology using DNA (Group XII), a method for preventing NF-κB associated pathology using protein (Group XIII), a method for identifying a ligand that binds to an NF-κB and TRAF2 binding protein by affinity chromatography (Group XIV), a method for identifying a ligand that binds to an NF-κB and TRAF2 binding protein by two-hybrid analysis (Group XV), a method for identifying a ligand that modulates TRAF2 and/or NEMO activity (Group XVI), a method to identify a ligand that modulates the activity modulated by a protein that binds NF-κB or TRAF2 (Group XVII) and a method for identifying a molecule that modulates NAP directly or indirectly (Group XVIII) because the recited methods utilize molecules that are different from the antibody in practicing the methods, and thus have different modes of operation and resulting functions. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group V and Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced using a materially different product, such as a DNA molecule. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Groups VI- XVIII are each unrelated to the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and functions. In each case, the methods either use a materially different molecule with a distinct chemical structure in the practice of the method (lending itself towards a different method step), have a different intended goal (such as the identification of a molecule with a distinct function), or the methods recite different unrelated steps. A search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II and so on, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
August 21, 2002

DAVID GUZO
PRIMARY EXAMINER